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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,312	02/12/2002	P.R. Suresh Samuel	P-5314	8416
26253	7590	10/29/2003	EXAMINER	
BECTON, DICKINSON AND COMPANY 1 BECTON DRIVE FRANKLIN LAKES, NJ 07417-1880			BRYANT, DAVID P	
		ART UNIT		PAPER NUMBER
		3726		
DATE MAILED: 10/29/2003 5				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)
	10/074,312	SAMUEL, P.R. SURESH
	Examiner David P. Bryant	Art Unit 3726

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 September 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
 - 4a) Of the above claim(s) 25-29 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5 and 11-24 is/are rejected.
- 7) Claim(s) 6-10 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

<ol style="list-style-type: none"> 1)<input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2)<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3)<input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 	<ol style="list-style-type: none"> 4)<input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ 5)<input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6)<input type="checkbox"/> Other: _____
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DETAILED ACTION

Election/Restrictions

Applicant's election of Species A, readable on claims 1-24, in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 25-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23:

In lines 2-3, "said passage" lacks proper antecedent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 11-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Case (U.S. Patent No. 5,351,381).

Claim 1: In Figures 1-4, Case depicts an apparatus **10** for removing a needle **47** from a medical device **36**, comprising:

a container **12** defining a chamber, said container including a container top **68** having an aperture **34** communicating with said chamber;
a needle removing fixture **22/28** mounted to said container and rotatable with respect thereto free of shearing surfaces, said needle removing fixture being positioned at least partially within said chamber and including a passage (defined between gears **22** and **28** in Figure 2) for receiving a needle **47** extending through said aperture **34** in said container top **68**; and
means **44** for rotating said needle removing fixture.

Claims 2 and 3: As shown in Figure 2, the passage between gears **22** and **28** is axially aligned with aperture **34**, and extends entirely through the needle removing fixture.

Claims 4 and 5: In Figures 1-4, note handle **46**, which extends outside the container.

Claim 11: As shown in Figure 2, the “axis” of the passage between gears **22** and **28** is substantially perpendicular to the container top **68**.

Claim 12: Case teaches an apparatus **10** for removing a needle **47** from a medical device **36**, comprising:

means **37** for maintaining said medical device in a substantially stationary position;
means **22, 28** for retaining a needle attached to a medical device; and

means 44 for rotating said retaining means about a generally horizontal axis 26 free of shearing surfaces.

Claim 13: In Figure 1, note means 12 for storing the used needles 47.

Claim 14: In Figure 2, note the passage defined between gears 22 and 28, plate 68, and aperture opening 34.

Claim 15: Case teaches a method of removing a needle 47 from a medical device 36, comprising:

inserting said needle of said medical device into a passage of a needle removing fixture 22/28 (see Figure 2), and

rotating (clockwise, as shown by the arrow in Figure 2) said needle removing fixture about an axis 26 while maintaining said medical device in a substantially stationary position, thereby removing said needle from said medical device without shearing thereof (see column 5, lines 7-27, for the operation of the device).

Claim 16: See Figure 1, which depicts used needles 47 captured in container 12.

Claim 17: In Figure 2, note aperture 34.

Claim 18: As shown in Figure 2, barrel 42 of medical device 36 engages a funnel-shaped opening 37 in container top 68.

Claim 19: Figure 2 depicts the passage and the aperture 34 in axial alignment.

Claim 20: As shown in Figures 1-4, the needle removing fixture is rotated about axis 26 using lever 44 and handle 46.

Claims 21-24: In Figure 2, Case teaches a method of removing a metal needle 47 from a plastic hub 42 of a medical device 36, comprising:

securing said medical device in a substantially stationary position whereby said needle is located at a predetermined position (note the medical device positioned within a funnel-shaped opening 37 in container top 68, with the needle being passed through an aperture 34 in the top and inserted in a passage between needle removing gears 22 and 28);

disconnecting said metal needle from said plastic hub without shearing of said needle while simultaneously deforming said metal needle to prevent reuse thereof (see column 5, lines 7-27, for the operation of the device, and Figure 1, which depicts the deformed needles captured in a container 12).

Allowable Subject Matter

Claims 6-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, for the following reasons:

The prior art fails to teach or suggest the combination of elements in claims 4 and 6, i.e. a *handle* for rotating the needle removing fixture and a needle removing fixture which is rotatably mounted *to the container top*. Case (U.S. Patent No. 5,351,381) teaches the handle, but the needle removing fixture is not mounted to the container top. Thead et al. (U.S. Patent No. 4,986,811) and Han (U.S. Patent No. 5,312,346) teach a rotatable needle removing fixture mounted to a container top, but do not teach a handle.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's

disclosure. Each reference discloses a method and apparatus for removing and/or destroying a needle attached to a hypodermic syringe.

Telephone inquiries regarding the status of this application, or other general questions, by persons entitled to the information, should be directed to the group clerical personnel. In as much as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information. M.P.E.P. 203.08. The Group clerical receptionist number is (703) 308-1148.

If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers or other general questions should be directed to Tech Center 3700 Customer Service at (703) 306-5648, or fax (703) 872-9301 or by email to CustomerService3700@uspto.gov.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **David Bryant** whose telephone number is (703) 308-1859. Draft amendments or proposed changes to the application may be faxed directly to the examiner at any time via RightFAX at (703) 746-4213 (formal inquiries or responses should NEVER be faxed to this number). The examiner can normally be reached on **Mondays-Thursdays from 6:30 AM to 5:00 PM.**

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Vo can be reached on 703-308-1789. The official fax phone number for the organization where this application or proceeding is 703-872-9306 for all communications (including After Final communications).

Other helpful telephone numbers are listed for applicant's benefit.

Allowed Files & Publication	(703) 308-6789 or (888) 786-0101
Assignment Branch	(703) 308-9723
Certificates of Correction	(703) 305-8309
Drawing Corrections/Draftsman	(703) 305-8404/8335
Petitions/Special Programs	(703) 305-9285
Terminal Disclaimers	(703) 305-8408
PCT Help Desk	(703) 305-3257

If the information desired is not provided above, or a number has been changed, please call the general information help line below.

Information Help line 1-800-786-9199
Internet PTO-Home Page <http://www.uspto.gov/>



David P. Bryant
Primary Examiner
Art Unit 3726